

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

**ERFINDERGEMEINSCHAFT UROPEP  
GbR,**

**Plaintiff,**

**vs.**

**ELI LILLY AND COMPANY, and  
BROOKSHIRE BROTHERS, INC.,**

**Defendants.**

**CIVIL ACTION No. 2:15-cv-01202-WCB**

**Judge: Hon. William C. Bryson**

**DEFENDANT ELI LILLY AND COMPANY'S MOTION FOR PROTECTIVE ORDER**

Pursuant to Fed. R. Civ. P. 26(c), defendant Eli Lilly and Company (“Lilly”) requests that the Court enter a protective order striking Plaintiff Erfindergemeinschaft UroPep GbR’s First Set of Interrogatories and requiring UroPep to serve new interrogatories that comply with the Federal Rules and the Court’s Discovery Order in this case (Dkt. 64).

**I. BACKGROUND**

UroPep asserts in this case that Lilly’s drug product, Cialis®, infringes claims 1 and 3 of U.S. Patent No. 8,791,124 (“the ‘124 Patent”). Both claims purport to claim a method for the prophylaxis or treatment of benign prostatic hyperplasia (BPH) by administering effective amount of an inhibitor of phosphodiesterase (PDE) V to a patient in need thereof.

On March 18, 2016, UroPep served its First Set of Interrogatories to Defendant Eli Lilly and Company (the “Interrogatories”). A copy of the Interrogatories is attached as Exhibit 1 to the Declaration of Todd Vare. Although the Interrogatories are numbered 1-18, many of UroPep’s

interrogatories contain discrete subparts that ask independent questions that are severable from one another and require separate and distinct review and response.

For example, the first part of Interrogatory No. 1 asks Lilly to “[d]escribe in full and complete detail the mechanism underlying the pharmaceutical effects of Cialis for treatment of ED, including the method of action, molecules, pathways, and reactions involved.” The second part of Interrogatory No. 1 asks Lilly to “identify all Persons involved in the design, testing or other aspects of developing Cialis for treating ED and all documents by Bates number concerning such mechanism including notebooks, experimental results, clinical testing results, non-clinical testing results, computer modeling results, relevant communications, and literatures.” These two parts of Interrogatory No. 1 call for separate answers that do not overlap. One would “describe in full and complete detail the mechanism underlying the pharmaceutical effects of Cialis for treatment of ED” without ever identifying any person “involved in the design, testing or other aspects of developing Cialis for treating ED”—and vice versa.<sup>1</sup>

UroPep’s practice of combining two or more distinct questions in a single purported “interrogatory” is not limited to Interrogatory No. 1. Lilly’s conservative analysis of UroPep’s Interrogatories indicates that eight of UroPep’s 18 interrogatories actually contain at least 28 discrete interrogatories subparts:

| Interrogatory | Number of discrete subparts |
|---------------|-----------------------------|
| 1             | 2                           |
| 2             | 2                           |
| 3             | 2                           |
| 4             | 1                           |
| 5             | 3                           |
| 6             | 1                           |

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<sup>1</sup> Lilly has other objections to UroPep’s interrogatories, including on grounds of relevancy, over breadth, ambiguity, and the like. Lilly is serving a separate set of objections on UroPep discussing these objections, which are not part of this motion.

| Interrogatory | Number of discrete subparts |
|---------------|-----------------------------|
| 7             | 1                           |
| 8             | 1                           |
| 9             | 1                           |
| 10            | 6                           |
| 11            | 1                           |
| 12            | 1                           |
| 13            | 1                           |
| 14            | 4                           |
| 15            | 4                           |
| 16            | 5                           |
| 17            | 1                           |
| 18            | 1                           |

As discussed in further detail below, there are good reasons why these conservative numbers actually undercount the number of discrete subparts in UroPep's Interrogatories. All told, however, UroPep's has served *at least* 38 Interrogatories in its numbered set of 18, which substantially exceeds the limit of 25 interrogatories permitted to be served on Lilly under the Court's Discovery Order (*see* Dkt. 64).

On April 4, 2016, counsel for Lilly sent a letter to counsel for UroPep outlining Lilly's concerns with the number and scope of UroPep's Interrogatories and requesting a meet-and-confer to try to come to an amicable solution. Ex. A, Vare Decl., Ex. 2. UroPep's counsel did not initially respond to Lilly's request to meet and confer, so Lilly's counsel sent a follow-up email to UroPep's counsel on April 11, 2016 again requesting a meet-and-confer. Ex. A, Vare Decl., Ex. 3. UroPep's counsel responded to the April 11 email and a meet-and-confer was held on that date via teleconference.

During the teleconference, counsel for Lilly offered to work with counsel for UroPep to narrow the overly broad interrogatories and to determine which of the subparts should be counted as UroPep's 25 interrogatories. Counsel for UroPep summarily dismissed Lilly's objections to the scope of UroPep's interrogatories and to the number of discrete subparts. On

April 12, 2016, counsel for Lilly followed up with an email outlining Lilly's objections and identifying, for a subsequent meet-and-confer discussion, certain interrogatories that Lilly contended contained multiple discrete subparts. Ex. A, Vare Decl., Ex. 4. UroPep's counsel responded on April 13, 2016, stating that UroPep would respond to Lilly's subpart objections via letter "in relatively due course." Ex. A, Vare Decl., Ex. 5. As of the filing of this motion, no response has been received from UroPep.

Lilly has served its objections to UroPep's Interrogatories concurrent with this Motion for Protective Order. Since there is a dispute regarding the proper number of interrogatories, Lilly will further respond to the interrogatories that are maintained or re-served after the resolution of this motion.

## **II. ARGUMENT**

### **A. Applicable Legal Standards**

As amended, Rule 26(c)(1) authorizes protective orders, for good cause shown,

[T]o protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following: (A) forbidding the disclosure or discovery; (B) specifying terms, including time and place or allocation of expenses, for the disclosure or discovery; (C) prescribing a discovery method other than the one selected by the party seeking discovery; (D) forbidding inquiry into certain matters, or limiting the scope of disclosure or discovery to certain matters; (E) designating the persons who may be present while the discovery is conducted; (F) requiring that a deposition be sealed and opened only on court order; (G) requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way; and (H) requiring that the parties simultaneously file specified documents or information in sealed envelopes, to be opened as the court directs.

Fed. R. Civ. P. 26(c)(1).

"[T]he burden is upon [the moving party] to show the necessity of ... [a protective order's] issuance, which contemplates a particular and specific demonstration of fact as distinguished from stereotyped and conclusory statements." *In re Terra Int'l*, 134 F.3d 302, 306

(5th Cir.1998) (citation omitted). A protective order is warranted in those instances in which the party seeking it demonstrates good cause and a specific need for protection. *See Landry v. Air Line Pilots Ass'n*, 901 F.2d 404, 434-435 (5th Cir.1990). The Court has broad discretion in determining whether to grant a motion for a protective order. *See Harris v. Amoco Prod. Co.*, 768 F.2d 669, 684 (5th Cir.1985). "The trial court is in the best position to weigh fairly the competing needs and interests of parties affected by discovery." *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36, 104 S.Ct. 2199, 81 L.Ed.2d 17 (1984).

Moreover, "[o]n motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that: (i) the discovery sought ...can be obtained from some other source that is more convenient, less burdensome, or less expensive." Fed. R. Civ. P. 26(b)(2)(C)(i). Federal Rules of Civil Procedure Rules 26(b), as amended effective December 1, 2015, provides that,

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. 26(b)(1).

**B. The Discovery Order In This Case Restricts UroPep to 25 Interrogatories For Each Defendant**

The Discovery Order limits UroPep to 25 interrogatories for each defendant: 25 for Defendant Eli Lilly and Company and 25 for Defendant Brookshire Brothers, Inc. *See* Dkt. 64. Fed. R. Civ. P. 33(a)(1) defines interrogatories as "including all discrete subparts." In this District, when "the first question can be answered fully and completely without answering the

second question, then the second question is totally independent of the first and not factually subsumed within [it].” *FTC v. Think All Publishing, LLC*, No. 4:07-cv-011, 2008 WL 687455, \*1 (E.D. Tex. Mar. 11, 2008) (citation omitted, brackets in original). Thus, the test for whether an interrogatory contains discrete subparts is whether one part of the interrogatory can be fully and completely answered independent of the other part.

**C. UroPep’s First Set Of Interrogatories To Lilly Contain At Least 38 Discrete Interrogatories**

At issue in this Motion is UroPep’s First Set of Interrogatories, which are directed only to Defendant Eli Lilly and Company. Although UroPep’s Interrogatories are numbered 1-18, at least eight Interrogatories (Nos. 1, 2, 3, 5, 10, 14,15 and 16) contain discrete subparts. Lilly discusses each of these Interrogatories below; in the interest of conserving space, the full text of each interrogatory will not be repeated in this motion. The Interrogatories are attached as Exhibit 1 to the Declaration of Todd Vare.

**Interrogatory No. 1**

This interrogatory contains two discrete subparts under the *FTC* test. The first part of Interrogatory No. 1 asks for a scientific narrative of mechanism that underlies the pharmacological effects of Cialis for the treatment of ED. This (already overly broad) request seeks information regarding the mechanism of Cialis, regardless of whether the understanding of the mechanism came from Lilly’s research or the thousands of papers and research studies prepared by others throughout the world. The second part of the interrogatory seeks information regarding, and identifications of, *all* persons<sup>2</sup> and *all* documents who were involved in the design, testing and development of Cialis for treating ED.

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<sup>2</sup> UroPep defines “Person” or “Persons” to include “not only natural individuals, but also, without limitation, firms, partnerships, associations, corporations, and other legal entities, and divisions, departments, or other units thereof.”

These two subparts can be completely answered independently without any factual overlap. In fact, there is no reason to identify particular researchers at Lilly or elsewhere in describing the pharmacological effects of Cialis for the treatment of ED. Similarly, there is no reason to discuss the pharmacological effects of Cialis in identifying persons or documents relating to specific tests that may have been performed. Interrogatory No. 1 should be considered at least two interrogatories.

**Interrogatory No. 2.**

This interrogatory contains two discrete subparts. As with Interrogatory No. 1, the first part asks for a theoretical discussion of mechanism that underlies the pharmacological effects of Cialis for the treatment of BPH. This broad interrogatory seeks information regarding the mechanism of Cialis regardless of whether the understanding of the mechanism came from Lilly's research or the thousands of papers and research studies prepared by others throughout the world. The second part of the interrogatory seeks information regarding, and identifications of, *all* persons and *all* documents who were involved in the design, testing and development of Cialis for treating ED. These two subparts can be completely answered independently, without factual overlap, and Interrogatory No. 2 should also be counted as at least two interrogatories.

**Interrogatory No. 3**

This interrogatory contains *at least* two discrete subparts requesting information comparing Cialis to eleven other PDE enzymes—and, under a subpart counting method endorsed by a sister Court, has as many as *twenty-two* discrete subparts. The first part of this Interrogatory asks for a comparison of the ability of Cialis to inhibit PDE V relative to its ability inhibit eleven other PDE enzymes. The second part asks for information regarding the design of “all testing” of Cialis’s inhibition of eleven other PDE enzymes, as well as “all Persons” and “all Documents”

relating to all such testing. These two subparts can be completely answered independently and should be considered at least two interrogatories.

Thus, Interrogatory No. 3 has at least two discrete subparts. Under the Court's reasoning in *Orion IP, LLC v. Staples, Inc.*, 2:04-cv-297-LED (E.D. Tex. July 7, 2005)(attached as Exhibit 6 to Declaration of Todd Vare), however, this Interrogatory actually constitutes *twenty-two* discrete subparts. In *Orion*, Judge Davis held that an interrogatory that requested a detailed analysis of different pieces of prior art was, in essence, a set of discrete interrogatories, each directed to a different piece of prior art. *Id.*, at pp. 1-2. Similarly, in this interrogatory, UroPep requests a comparison, "in full and complete detail," of Cialis to eleven different PDE enzymes and also requests detailed information regarding Lilly's research in regard to those eleven PDE enzymes. Each of the two requests contained in Interrogatory No. 3 asks Lilly to compare Cialis to each of the eleven PDE distinct enzymes. Each one of these eleven distinct PDE enzymes has a separate and independent biological function, and were discovered and isolated at different times over at least the last 30 years or so. Although Lilly has conservatively counted Interrogatory No. 2 as two having two discrete subparts for the purposes of this motion, the law supports counting it as 22 distinct subparts for the purposes of the Court's Discovery Order.<sup>3</sup>

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<sup>3</sup> Interrogatory No. 3 also demonstrates the incredible breadth and burden associated with UroPep's First Interrogatories—which is only exacerbated by the excessive number of discrete subparts. Answering Interrogatory No. 3 would require Lilly to review hundreds of thousands of pages of internal documents relating to the research of Cialis for over 20 years—and review an even greater number of external research papers, scientific literature, and studies over an ever greater length of time relating to other PDE enzymes—and then prepare a separate analysis comparing Cialis' ability to inhibit PDE5 to its ability to inhibit 11 other PDE enzymes. Moreover, the ability of Cialis to inhibit PDE V in comparison to its ability to inhibit other PDE enzymes is not relevant to the '124 Patent claims, which recite simply "an inhibitor of phosphodiesterase (PDE) V."

**Interrogatory No. 5**

This interrogatory contains at least three discrete subparts. First, it asks for a description of Lilly's knowledge of the asserted patent and three related patent applications. Second, it asks for a detailed description of Lilly's attempts to design around the asserted patent or otherwise avoid infringement. Third, it requests a description of how knowledge of the asserted patent or UroPep's patent applications effected Lilly's research, marketing and sales operations. These three subparts are three separate questions that can be completely answered independently of one another and should be considered as three interrogatories.

**Interrogatory No. 10**

This interrogatory contains at least six discrete subparts. The first part of the interrogatory asks for a detailed description of Lilly's basis for filing three different patent applications. The second part of the interrogatory asks for a description of any testing or computer modeling performed by Lilly in regard to the subject matter of the three patent applications. The first and second parts of Interrogatory No. 10 can be completely answered independently of one another. Moreover, since this interrogatory requests detailed answers for three different applications, it should be considered to be at least six interrogatories (two questions per distinct patent application).

**Interrogatory No. 14**

This interrogatory contains at least four discrete subparts. The first part of the interrogatory requests a description "in full and complete detail" of Lilly's costs, revenues and expenditures for Cialis for the treatment of ED alone. The second part asks for this financial information for Cialis for the treatment of ED and BPH concurrently. The third part asks for this financial information for Cialis for the treatment of BPH alone. The fourth part requests a

description of how Lilly's sales and profits are recorded. These four subparts can be completely answered independently and should be counted as four interrogatories.

**Interrogatory No. 15**

This interrogatory contains at least four discrete subparts. Similar to Interrogatory No. 14, the first part of the interrogatory requests a "breakdown" of Lilly's costs, revenues and expenditures for sales of Cialis for the treatment of ED alone. The second part asks for this financial information for Cialis for the treatment of ED and BPH concurrently. The third part asks for this financial information for Cialis for the treatment of BPH alone. The fourth part requests that Lilly identify and describe each entity involved in each channel of sales Cialis. These four subparts can be completely answered independently and should be considered four interrogatories.

**Interrogatory No. 16**

This interrogatory contains at least five discrete subparts. Similar to Interrogatory No. 14, the first part of the interrogatory requests a description of the actual price and projected price of Cialis for the treatment of ED alone. The second part asks for this financial information for Cialis for the treatment of ED and BPH concurrently. The third part asks for this financial information for Cialis for the treatment of BPH alone. The fourth part requests a description of the rationale underlying all changes of the price for Cialis. The fifth part requests that Lilly identify all contracts with purchasers of Cialis. These five subparts can be completely answered independently and should be considered four interrogatories.

**III. CONCLUSION**

When all discrete subparts are counted, UroPep's Interrogatories exceed the limit imposed by the Discovery Order by at least 13 interrogatories—if not considerably more. Lilly has offered to work with UroPep to get UroPep the information that it needs to move its case

forward, but in a way that does not violate the Discovery Order. UroPep, however, has simply ignored Lilly's request to meet and confer on this issue to avoid this motion. Therefore, Lilly respectfully asks that the Court grant its Motion for Protective Order and require that UroPep serve new interrogatories that comply with the requirements of the Federal Rules and, specifically, the limitation to 25 interrogatories under the Discovery Order.

Dated: April 21, 2016

By: /s/*Jon B. Hyland*

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**CERTIFICATE OF SERVICE**

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this motion was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email and/or fax, on this the 21st day of April, 2016.

*/s/ Jon B. Hyland* \_\_\_\_\_

Jon B. Hyland

**CERTIFICATE OF CONFERENCE**

The undersigned certifies that on April 11, 2016, counsel for Plaintiff and counsel for Lilly conducted a conference via telephone with Plaintiff's counsel regarding the above motion. During this call Plaintiff informed Lilly that this motion is **OPPOSED**.

*/s/ Jon B. Hyland* \_\_\_\_\_

Jon B. Hyland